

108TH CONGRESS  
1ST SESSION

# S. 313

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IN THE HOUSE OF REPRESENTATIVES

JUNE 4, 2003

Referred to the Committee on Energy and Commerce

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## AN ACT

To amend the Federal Food, Drug, and Cosmetic Act to  
establish a program of fees relating to animal drugs.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Animal Drug User Fee  
5       Act of 2003”.

1 **SEC. 2. FINDINGS.**

2 Congress finds as follows:

3 (1) Prompt approval of safe and effective new  
4 animal drugs is critical to the improvement of ani-  
5 mal health and the public health.

6 (2) Animal health and the public health will be  
7 served by making additional funds available for the  
8 purpose of augmenting the resources of the Food  
9 and Drug Administration that are devoted to the  
10 process for review of new animal drug applications.

11 (3) The fees authorized by this title will be  
12 dedicated toward expediting the animal drug devel-  
13 opment process and the review of new and supple-  
14 mental animal drug applications and investigational  
15 animal drug submissions as set forth in the goals  
16 identified, for purposes of part 3 of subchapter C of  
17 chapter VII of the Federal Food, Drug, and Cos-  
18 metic Act, in the letters from the Secretary of  
19 Health and Human Services to the Chairman of the  
20 Committee on Energy and Commerce of the House  
21 of Representatives and the Chairman of the Com-  
22 mittee on Health, Education, Labor, and Pensions  
23 of the Senate as set forth in the Congressional  
24 Record.

1 **SEC. 3. FEES RELATING TO ANIMAL DRUGS.**

2 Subchapter C of chapter VII of the Federal Food,  
3 Drug and Cosmetic Act (21 U.S.C. 379f et seq.) is amend-  
4 ed by adding at the end the following part:

5 **“PART 4—FEES RELATING TO ANIMAL DRUGS**

6 **“SEC. 739. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**  
7 **FEES.**

8 “(a) DEFINITIONS.—For purposes of this sub-  
9 chapter:

10 “(1) The term ‘animal drug application’ means  
11 an application for approval of any new animal drug  
12 submitted under section 512(b)(1). Such term does  
13 not include either a new animal drug application  
14 submitted under section 512(b)(2) or a supplemental  
15 animal drug application.

16 “(2) The term ‘supplemental animal drug appli-  
17 cation’ means—

18 “(A) a request to the Secretary to approve  
19 a change in an animal drug application which  
20 has been approved; or

21 “(B) a request to the Secretary to approve  
22 a change to an application approved under sec-  
23 tion 512(c)(2) for which data with respect to  
24 safety or effectiveness are required.

25 “(3) The term ‘animal drug product’ means  
26 each specific strength or potency of a particular ac-

1        tive ingredient or ingredients in final dosage form  
2        marketed by a particular manufacturer or dis-  
3        tributor, which is uniquely identified by the labeler  
4        code and product code portions of the national drug  
5        code, and for which an animal drug application or  
6        a supplemental animal drug application has been ap-  
7        proved.

8            “(4) The term ‘animal drug establishment’  
9        means a foreign or domestic place of business which  
10       is at one general physical location consisting of one  
11       or more buildings all of which are within 5 miles of  
12       each other, at which one or more animal drug prod-  
13       ucts are manufactured in final dosage form.

14           “(5) The term ‘investigational animal drug sub-  
15       mission’ means—

16            “(A) the filing of a claim for an investiga-  
17       tional exemption under section 512(j) for a new  
18       animal drug intended to be the subject of an  
19       animal drug application or a supplemental ani-  
20       mal drug application, or

21            “(B) the submission of information for the  
22       purpose of enabling the Secretary to evaluate  
23       the safety or effectiveness of an animal drug  
24       application or supplemental animal drug appli-  
25       cation in the event of their filing.

1           “(6) The term ‘animal drug sponsor’ means ei-  
2           ther an applicant named in an animal drug applica-  
3           tion, except for an approved application for which all  
4           subject products have been removed from listing  
5           under section 510, or a person who has submitted  
6           an investigational animal drug submission that has  
7           not been terminated or otherwise rendered inactive  
8           by the Secretary.

9           “(7) The term ‘final dosage form’ means, with  
10          respect to an animal drug product, a finished dosage  
11          form which is approved for administration to an ani-  
12          mal without substantial further manufacturing. Such  
13          term includes animal drug products intended for  
14          mixing in animal feeds.

15          “(8) The term ‘process for the review of animal  
16          drug applications’ means the following activities of  
17          the Secretary with respect to the review of animal  
18          drug applications, supplemental animal drug applica-  
19          tions, and investigational animal drug submissions:

20                 “(A) The activities necessary for the re-  
21                 view of animal drug applications, supplemental  
22                 animal drug applications, and investigational  
23                 animal drug submissions.

24                 “(B) The issuance of action letters which  
25                 approve animal drug applications or supple-

1           mental animal drug applications or which set  
2           forth in detail the specific deficiencies in animal  
3           drug applications, supplemental animal drug  
4           applications, or investigational animal drug sub-  
5           missions and, where appropriate, the actions  
6           necessary to place such applications, supple-  
7           ments or submissions in condition for approval.

8           “(C) The inspection of animal drug estab-  
9           lishments and other facilities undertaken as  
10          part of the Secretary’s review of pending animal  
11          drug applications, supplemental animal drug  
12          applications, and investigational animal drug  
13          submissions.

14          “(D) Monitoring of research conducted in  
15          connection with the review of animal drug ap-  
16          plications, supplemental animal drug applica-  
17          tions, and investigational animal drug submis-  
18          sions.

19          “(E) The development of regulations and  
20          policy related to the review of animal drug ap-  
21          plications, supplemental animal drug applica-  
22          tions, and investigational animal drug submis-  
23          sions.

24          “(F) Development of standards for prod-  
25          ucts subject to review.

1           “(G) Meetings between the agency and the  
2           animal drug sponsor.

3           “(H) Review of advertising and labeling  
4           prior to approval of an animal drug application  
5           or supplemental animal drug application, but  
6           not such activities after an animal drug has  
7           been approved.

8           “(9) The term ‘costs of resources allocated for  
9           the process for the review of animal drug applica-  
10          tions’ means the expenses incurred in connection  
11          with the process for the review of animal drug appli-  
12          cations for—

13           “(A) officers and employees of the Food  
14           and Drug Administration, contractors of the  
15           Food and Drug Administration, advisory com-  
16           mittees consulted with respect to the review of  
17           specific animal drug applications, supplemental  
18           animal drug applications, or investigational ani-  
19           mal drug submissions, and costs related to such  
20           officers, employees, committees, and contrac-  
21           tors, including costs for travel, education, and  
22           recruitment and other personnel activities,

23           “(B) management of information, and the  
24           acquisition, maintenance, and repair of com-  
25           puter resources,

1           “(C) leasing, maintenance, renovation, and  
 2           repair of facilities and acquisition, maintenance,  
 3           and repair of fixtures, furniture, scientific  
 4           equipment, and other necessary materials and  
 5           supplies, and

6           “(D) collecting fees under this section and  
 7           accounting for resources allocated for the re-  
 8           view of animal drug applications, supplemental  
 9           animal drug applications, and investigational  
 10          animal drug submissions.

11          “(10) The term ‘adjustment factor’ applicable  
 12          to a fiscal year refers to the formula set forth in sec-  
 13          tion 735(8) with the base or comparator year being  
 14          2003.

15          “(11) The term ‘affiliate’ refers to the defini-  
 16          tion set forth in section 735(9).

17          “(b) TYPES OF FEES.—Beginning in fiscal year  
 18          2004, the Secretary shall assess and collect fees in accord-  
 19          ance with this section as follows:

20                 “(1) ANIMAL DRUG APPLICATION AND SUPPLE-  
 21                 MENT FEE.—

22                 “(A) IN GENERAL.—Each person that sub-  
 23                 mits, on or after September 1, 2003, an animal  
 24                 drug application or a supplemental animal drug  
 25                 application shall be subject to a fee as follows:



1 “(i) A fee established in subsection (c)  
2 for an animal drug application; and

3 “(ii) A fee established in subsection  
4 (c) for a supplemental animal drug appli-  
5 cation for which safety or effectiveness  
6 data are required, in an amount that is  
7 equal to 50 percent of the amount of the  
8 fee under clause (i).

9 “(B) PAYMENT.—The fee required by sub-  
10 paragraph (A) shall be due upon submission of  
11 the animal drug application or supplemental  
12 animal drug application.

13 “(C) EXCEPTION FOR PREVIOUSLY FILED  
14 APPLICATION OR SUPPLEMENT.—If an animal  
15 drug application or a supplemental animal drug  
16 application was submitted by a person that paid  
17 the fee for such application or supplement, was  
18 accepted for filing, and was not approved or  
19 was withdrawn (without a waiver or refund),  
20 the submission of an animal drug application or  
21 a supplemental animal drug application for the  
22 same product by the same person (or the per-  
23 son’s licensee, assignee, or successor) shall not  
24 be subject to a fee under subparagraph (A).

1           “(D) REFUND OF FEE IF APPLICATION RE-  
2           FUSED FOR FILING.—The Secretary shall re-  
3           fund 75 percent of the fee paid under subpara-  
4           graph (B) for any animal drug application or  
5           supplemental animal drug application which is  
6           refused for filing.

7           “(E) REFUND OF FEE IF APPLICATION  
8           WITHDRAWN.—If an animal drug application or  
9           a supplemental animal drug application is with-  
10          drawn after the application or supplement was  
11          filed, the Secretary may refund the fee or por-  
12          tion of the fee paid under subparagraph (B) if  
13          no substantial work was performed on the ap-  
14          plication or supplement after the application or  
15          supplement was filed. The Secretary shall have  
16          the sole discretion to refund the fee under this  
17          paragraph. A determination by the Secretary  
18          concerning a refund under this paragraph shall  
19          not be reviewable.

20          “(2) ANIMAL DRUG PRODUCT FEE.—Each per-  
21          son—

22               “(A) who is named as the applicant in an  
23               animal drug application or supplemental animal  
24               drug application for an animal drug product

1           which has been submitted for listing under sec-  
2           tion 510, and

3                 “(B) who, after September 1, 2003, had  
4           pending before the Secretary an animal drug  
5           application or supplemental animal drug appli-  
6           cation;

7           shall pay for each such animal drug product the an-  
8           nual fee established in subsection (c). Such fee shall  
9           be payable for the fiscal year in which the animal  
10          drug product is first submitted for listing under sec-  
11          tion 510, or is submitted for relisting under section  
12          510 if the animal drug product has been withdrawn  
13          from listing and relisted. After such fee is paid for  
14          that fiscal year, such fee shall be payable on or be-  
15          fore January 31 of each year. Such fee shall be paid  
16          only once for each animal drug product for a fiscal  
17          year in which the fee is payable.

18                 “(3) ANIMAL DRUG ESTABLISHMENT FEE.—

19          Each person—

20                 “(A) who owns or operates, directly or  
21          through an affiliate, an animal drug establish-  
22          ment, and

23                 “(B) who is named as the applicant in an  
24          animal drug application or supplemental animal  
25          drug application for an animal drug product

1           which has been submitted for listing under sec-  
2           tion 510, and

3                 “(C) who, after September 1, 2003, had  
4           pending before the Secretary an animal drug  
5           application or supplemental animal drug appli-  
6           cation,

7           shall be assessed an annual fee established in sub-  
8           section (c) for each animal drug establishment listed  
9           in its approved animal drug application as an estab-  
10          lishment that manufactures the animal drug product  
11          named in the application. The annual establishment  
12          fee shall be assessed in each fiscal year in which the  
13          animal drug product named in the application is as-  
14          sessed a fee under paragraph (2) unless the animal  
15          drug establishment listed in the application does not  
16          engage in the manufacture of the animal drug prod-  
17          uct during the fiscal year. The fee shall be paid on  
18          or before January 31 of each year. The establish-  
19          ment shall be assessed only one fee per fiscal year  
20          under this section, provided, however, that where a  
21          single establishment manufactures both animal drug  
22          products and prescription drug products, as defined  
23          in section 735(3), such establishment shall be as-  
24          sessed both the animal drug establishment fee and

1 the prescription drug establishment fee, as set forth  
 2 in section 736(a)(2), within a single fiscal year.

3 “(4) ANIMAL DRUG SPONSOR FEE.—Each per-  
 4 son—

5 “(A) who meets the definition of an animal  
 6 drug sponsor within a fiscal year; and

7 “(B) who, after September 1, 2003, had  
 8 pending before the Secretary an animal drug  
 9 application, a supplemental animal drug appli-  
 10 cation, or an investigational animal drug sub-  
 11 mission,

12 shall be assessed an annual fee established under  
 13 subsection (c). The fee shall be paid on or before  
 14 January 31 of each year. Each animal drug sponsor  
 15 shall pay only one such fee each fiscal year.

16 “(c) FEE AMOUNTS.—Except as provided in sub-  
 17 section (b)(1) and subsections (d), (e), (g), and (h), the  
 18 fees required under subsection (b) shall be established to  
 19 generate fee revenue amounts as follows:

20 “(1) TOTAL FEE REVENUES FOR APPLICATION  
 21 AND SUPPLEMENT FEES.—The total fee revenues to  
 22 be collected in animal drug application fees under  
 23 subsection (b)(1)(A)(i) and supplemental animal  
 24 drug application fees under subsection (b)(1)(A)(ii)  
 25 shall be \$1,250,000 in fiscal year 2004, \$2,000,000

1 in fiscal year 2005, and \$2,500,000 in fiscal years  
2 2006, 2007, and 2008.

3 “(2) TOTAL FEE REVENUES FOR PRODUCT  
4 FEES.—The total fee revenues to be collected in  
5 product fees under subsection (b)(2) shall be  
6 \$1,250,000 in fiscal year 2004, \$2,000,000 in fiscal  
7 year 2005, and \$2,500,000 in fiscal years 2006,  
8 2007, and 2008.

9 “(3) TOTAL FEE REVENUES FOR ESTABLISH-  
10 MENT FEES.—The total fee revenues to be collected  
11 in establishment fees under subsection (b)(3) shall  
12 be \$1,250,000 in fiscal year 2004, \$2,000,000 in fis-  
13 cal year 2005, and \$2,500,000 in fiscal years 2006,  
14 2007, and 2008.

15 “(4) TOTAL FEE REVENUES FOR SPONSOR  
16 FEES.—The total fee revenues to be collected in  
17 sponsor fees under subsection (b)(4) shall be  
18 \$1,250,000 in fiscal year 2004, \$2,000,000 in fiscal  
19 year 2005, and \$2,500,000 in fiscal years 2006,  
20 2007, and 2008.

21 “(d) ADJUSTMENTS.—

22 “(1) INFLATION ADJUSTMENT.—The revenues  
23 established in subsection (b) shall be adjusted by the  
24 Secretary by notice, published in the Federal Reg-  
25 ister, for a fiscal year to reflect the greater of—

1           “(A) the total percentage change that oc-  
2           curred in the Consumer Price Index for all  
3           urban consumers (all items; United States city  
4           average) for the 12-month period ending June  
5           30 preceding the fiscal year for which fees are  
6           being established; or

7           “(B) the total percentage change for the  
8           previous fiscal year in basic pay under the Gen-  
9           eral Schedule in accordance with section 5332  
10          of title 5, United States Code, as adjusted by  
11          any locality-based comparability payment pur-  
12          suant to section 5304 of such title for Federal  
13          employees stationed in the District Columbia.

14       The adjustment made each fiscal year by this sub-  
15       section will be added on a compounded basis to the  
16       sum of all adjustments made each fiscal year after  
17       fiscal year 2004 under this subsection.

18           “(2) WORKLOAD ADJUSTMENT.—After the fee  
19       revenues are adjusted for inflation in accordance  
20       with paragraph (1), the fee revenues shall be further  
21       adjusted each fiscal year after fiscal year 2004 to re-  
22       flect changes in review workload. With respect to  
23       such adjustment:

24           “(A) This adjustment shall be determined  
25       by the Secretary based on a weighted average

1 of the change in the total number of animal  
2 drug applications, supplemental animal drug  
3 applications for which data with respect to safe-  
4 ty or effectiveness are required, manufacturing  
5 supplemental animal drug applications, inves-  
6 tigational animal drug study submissions, and  
7 investigational animal drug protocol submis-  
8 sions submitted to the Secretary. The Secretary  
9 shall publish in the Federal Register the fees  
10 resulting from this adjustment and the sup-  
11 porting methodologies.

12 “(B) Under no circumstances shall this  
13 workload adjustment result in fee revenues for  
14 a fiscal year that are less than the fee revenues  
15 for that fiscal year established in subsection (c),  
16 as adjusted for inflation under paragraph (1).

17 “(3) FINAL YEAR ADJUSTMENT.—For fiscal  
18 year 2008, the Secretary may further increase the  
19 fees to provide for up to 3 months of operating re-  
20 serves of carryover user fees for the process for the  
21 review of animal drug applications for the first 3  
22 months of fiscal year 2009 If the Food and Drug  
23 Administration has carryover balances for the pro-  
24 cess for the review of animal drug applications in ex-  
25 cess of 3 months of such operating reserves, then



1 this adjustment will not be made. If this adjustment  
2 is necessary, then the rationale for the amount of  
3 the increase shall be contained in the annual notice  
4 setting fees for fiscal year 2008

5 “(4) ANNUAL FEE SETTING.—The Secretary  
6 shall establish, 60 days before the start of each fis-  
7 cal year beginning after September 30, 2003, for  
8 that fiscal year, animal drug application fees, sup-  
9 plemental animal drug application fees, animal drug  
10 sponsor fees, animal drug establishment fees, and  
11 animal drug product fees based on the revenue  
12 amounts established under subsection (c) and the  
13 adjustments provided under this subsection.

14 “(5) LIMIT.—The total amount of fees charged,  
15 as adjusted under this subsection, for a fiscal year  
16 may not exceed the total costs for such fiscal year  
17 for the resources allocated for the process for the re-  
18 view of animal drug applications.

19 “(e) FEE WAIVER OR REDUCTION.—

20 “(1) IN GENERAL.—The Secretary shall grant a  
21 waiver from or a reduction of 1 or more fees as-  
22 sessed under subsection (b) where the Secretary  
23 finds that—

24 “(A) the assessment of the fee would  
25 present a significant barrier to innovation be-

1 cause of limited resources available to such per-  
2 son or other circumstances,

3 “(B) the fees to be paid by such person  
4 will exceed the anticipated present and future  
5 costs incurred by the Secretary in conducting  
6 the process for the review of animal drug appli-  
7 cations for such person,

8 “(C) the animal drug application or sup-  
9 plemental animal drug application is intended  
10 solely to provide for use of the animal drug  
11 in—

12 “(i) a Type B medicated feed (as de-  
13 fined in section 558.3(b)(3) of title 21,  
14 Code of Federal Regulations (or any suc-  
15 cessor regulation)) intended for use in the  
16 manufacture of Type C free-choice medi-  
17 cated feeds, or

18 “(ii) a Type C free-choice medicated  
19 feed (as defined in section 558.3(b)(4) of  
20 title 21, Code of Federal Regulations (or  
21 any successor regulation)),

22 “(D) the animal drug application or sup-  
23 plemental animal drug application is intended  
24 solely to provide for a minor use or minor spe-  
25 cies indication, or

1           “(E) the sponsor involved is a small busi-  
2           ness submitting its first animal drug applica-  
3           tion to the Secretary for review.

4           “(2) USE OF STANDARD COSTS.—In making the  
5           finding in paragraph (1)(B), the Secretary may use  
6           standard costs.

7           “(3) RULES FOR SMALL BUSINESSES.—

8           “(A) DEFINITION.—In paragraph (1)(E),  
9           the term “small business” means an entity that  
10          has fewer than 500 employees, including em-  
11          ployees of affiliates.

12          “(B) WAIVER OF APPLICATION FEE.—The  
13          Secretary shall waive under paragraph (1)(E)  
14          the application fee for the first animal drug ap-  
15          plication that a small business or its affiliate  
16          submits to the Secretary for review. After a  
17          small business or its affiliate is granted such a  
18          waiver, the small business or its affiliate shall  
19          pay application fees for all subsequent animal  
20          drug applications and supplemental animal  
21          drug applications for which safety or effective-  
22          ness data are required in the same manner as  
23          an entity that does not qualify as a small busi-  
24          ness.

1                   “(C) CERTIFICATION.—The Secretary shall  
2                   require any person who applies for a waiver  
3                   under paragraph (1)(E) to certify their quali-  
4                   fication for the waiver. The Secretary shall peri-  
5                   odically publish in the Federal Register a list of  
6                   persons making such certifications.

7                   “(f) EFFECT OF FAILURE TO PAY FEES.—An ani-  
8                   mal drug application or supplemental animal drug applica-  
9                   tion submitted by a person subject to fees under sub-  
10                  section (b) shall be considered incomplete and shall not  
11                  be accepted for filing by the Secretary until all fees owed  
12                  by such person have been paid. An investigational animal  
13                  drug submission under section 738(5)(B) that is sub-  
14                  mitted by a person subject to fees under subsection (b)  
15                  shall be considered incomplete and shall not be accepted  
16                  for review by the Secretary until all fees owed by such  
17                  person have been paid. The Secretary may discontinue re-  
18                  view of any animal drug application, supplemental animal  
19                  drug application or investigational animal drug submission  
20                  from a person if such person has not submitted for pay-  
21                  ment all fees owed under this section by 30 days after  
22                  the date upon which they are due.

23                  “(g) ASSESSMENT OF FEES.—

24                  “(1) LIMITATION.—Fees may not be assessed  
25                  under subsection (b) for a fiscal year beginning after

1       fiscal year 2003 unless appropriations for salaries  
2       and expenses of the Food and Drug Administration  
3       for such fiscal year (excluding the amount of fees  
4       appropriated for such fiscal year) are equal to or  
5       greater than the amount of appropriations for the  
6       salaries and expenses of the Food and Drug Admin-  
7       istration for the fiscal year 2003 (excluding the  
8       amount of fees appropriated for such fiscal year)  
9       multiplied by the adjustment factor applicable to the  
10      fiscal year involved.

11           “(2) AUTHORITY.—If the Secretary does not  
12      assess fees under subsection (b) during any portion  
13      of a fiscal year because of paragraph (1) and if at  
14      a later date in such fiscal year the Secretary may as-  
15      sess such fees, the Secretary may assess and collect  
16      such fees, without any modification in the rate, for  
17      animal drug applications, supplemental animal drug  
18      applications, investigational animal drug submis-  
19      sions, sponsors, animal drug establishments and ani-  
20      mal drug products at any time in such fiscal year  
21      notwithstanding the provisions of subsection (b) re-  
22      lating to the date fees are to be paid.

23           “(h) CREDITING AND AVAILABILITY OF FEES.—

24           “(1) IN GENERAL.—Fees authorized under sub-  
25      section (b) shall be collected and available for obliga-

1       tion only to the extent and in the amount provided  
 2       in advance in appropriations Acts. Such fees are au-  
 3       thorized to be appropriated to remain available until  
 4       expended. Such sums as may be necessary may be  
 5       transferred from the Food and Drug Administration  
 6       salaries and expenses appropriation account without  
 7       fiscal year limitation to such appropriation account  
 8       for salary and expenses with such fiscal year limita-  
 9       tion. The sums transferred shall be available solely  
 10      for the process for the review of animal drug appli-  
 11      cations.

12           “(2)   COLLECTIONS    AND    APPROPRIATION  
 13      ACTS.—

14           “(A) IN GENERAL.—The fees authorized  
 15      by this section—

16           “(i) shall be retained in each fiscal  
 17           year in an amount not to exceed the  
 18           amount specified in appropriation Acts, or  
 19           otherwise made available for obligation for  
 20           such fiscal year, and

21           “(ii) shall only be collected and avail-  
 22           able to defray increases in the costs of the  
 23           resources allocated for the process for the  
 24           review of animal drug applications (includ-  
 25           ing increases in such costs for an addi-

1           tional number of full-time equivalent posi-  
2           tions in the Department of Health and  
3           Human Services to be engaged in such  
4           process) over such costs, excluding costs  
5           paid from fees collected under this section,  
6           for fiscal year 2003 multiplied by the ad-  
7           justment factor.

8           “(B) COMPLIANCE.—The Secretary shall  
9           be considered to have met the requirements of  
10          subparagraph (A)(ii) in any fiscal year if the  
11          costs funded by appropriations and allocated for  
12          the process for the review of animal drug appli-  
13          cations—

14               “(i) are not more than 3 percent  
15               below the level specified in subparagraph  
16               (A)(ii); or

17               “(ii)(I) are more than 3 percent below  
18               the level specified in subparagraph (A)(ii),  
19               and fees assessed for the fiscal year fol-  
20               lowing the subsequent fiscal year are de-  
21               creased by the amount in excess of 3 per-  
22               cent by which such costs fell below the  
23               level specified in subparagraph (A)(ii); and

1 “(II) such costs are not more than 5  
 2 percent below the level specified in sub-  
 3 paragraph (A)(ii).

4 “(3) AUTHORIZATION OF APPROPRIATIONS.—  
 5 There are authorized to be appropriated for fees  
 6 under this section—

7 “(A) \$5,000,000 for fiscal year 2004;

8 “(B) \$8,000,000 for fiscal year 2005;

9 “(C) \$10,000,000 for fiscal year 2006;

10 “(D) \$10,000,000 for fiscal year 2007;

11 and

12 “(E) \$10,000,000 for fiscal year 2008;

13 as adjusted to reflect adjustments in the total fee  
 14 revenues made under this section and changes in the  
 15 total amounts collected by animal drug application  
 16 fees, supplemental animal drug application fees, ani-  
 17 mal drug sponsor fees, animal drug establishment  
 18 fees, and animal drug product fees.

19 “(4) OFFSET.—Any amount of fees collected  
 20 for a fiscal year under this section that exceeds the  
 21 amount of fees specified in appropriations Acts for  
 22 such fiscal year shall be credited to the appropria-  
 23 tion account of the Food and Drug Administration  
 24 as provided in paragraph (1), and shall be sub-  
 25 tracted from the amount of fees that would other-



1       wise be authorized to be collected under this section  
2       pursuant to appropriation Acts for a subsequent fis-  
3       cal year.

4       “(i) COLLECTION OF UNPAID FEES.—In any case  
5       where the Secretary does not receive payment of a fee as-  
6       sessed under subsection (b) within 30 days after it is due,  
7       such fee shall be treated as a claim of the United States  
8       Government subject to subchapter II of chapter 37 of title  
9       31, United States Code.

10       “(j) WRITTEN REQUESTS FOR WAIVERS, REDUC-  
11       TIONS, AND REFUNDS.—To qualify for consideration for  
12       a waiver or reduction under subsection (e), or for a refund  
13       of any fee collected in accordance with subsection (b), a  
14       person shall submit to the Secretary a written request for  
15       such waiver, reduction, or refund not later than 180 days  
16       after such fee is due.

17       “(k) CONSTRUCTION.—This section may not be con-  
18       strued to require that the number of full-time equivalent  
19       positions in the Department of Health and Human Serv-  
20       ices, for officers, employees, and advisory committees not  
21       engaged in the process of the review of animal drug appli-  
22       cations, be reduced to offset the number of officers, em-  
23       ployees, and advisory committees so engaged.

24       “(l) ABBREVIATED NEW DRUG APPLICATIONS.—The  
25       Secretary shall—

1 “(1) to the extent practicable, segregate the re-  
2 view of abbreviated new animal drug applications  
3 from the process for the review of animal drug appli-  
4 cations, and

5 “(2) adopt other administrative procedures to  
6 ensure that review times of abbreviated new animal  
7 drug applications do not increase from their current  
8 level due to activities under the user fee program.”.

9 **SEC. 4. ACCOUNTABILITY AND REPORTS.**

10 (a) PUBLIC ACCOUNTABILITY.—

11 (1) CONSULTATION.—In developing rec-  
12 ommendations to Congress for the goals and plans  
13 for meeting the goals for the process for the review  
14 of animal drug applications for the fiscal years after  
15 fiscal year 2008, and for the reauthorization of sec-  
16 tion 739 of the Federal Food, Drug, and Cosmetic  
17 Act (as added by section 3), the Secretary of Health  
18 and Human Services (referred to in this section as  
19 the “Secretary”) shall consult with the Committee  
20 on Energy and Commerce of the House of Rep-  
21 resentatives, the Committee on Health, Education,  
22 Labor, and Pensions of the Senate, appropriate sci-  
23 entific and academic experts, veterinary profes-  
24 sionals, representatives of consumer advocacy  
25 groups, and the regulated industry.

1           (2)     RECOMMENDATIONS.—The     Secretary  
2     shall—

3                   (A) publish in the Federal Register rec-  
4                   ommendations under paragraph (1), after nego-  
5                   tiations with the regulated industry;

6                   (B) present the recommendations to the  
7                   Committees referred to in that paragraph;

8                   (C) hold a meeting at which the public  
9                   may comment on the recommendations; and

10                  (D) provide for a period of 30 days for the  
11                  public to provide written comments on the rec-  
12                  ommendations.

13     (b) PERFORMANCE REPORTS.—Beginning with fiscal  
14     year 2004, not later than 60 days after the end of each  
15     fiscal year during which fees are collected under part 3  
16     of subchapter C of chapter VII of the Federal Food, Drug,  
17     and Cosmetic Act, the Secretary shall prepare and submit  
18     to the Committee on Energy and Commerce of the House  
19     of Representatives and the Committee on Health, Edu-  
20     cation, Labor, and Pensions of the Senate a report con-  
21     cerning the progress of the Food and Drug Administration  
22     in achieving the goals identified in the letters described  
23     in section 2(3) of this Act toward expediting the animal  
24     drug development process and the review of the new and  
25     supplemental animal drug applications and investigational

1 animal drug submissions during such fiscal year, the fu-  
2 ture plans of the Food and Drug Administration for meet-  
3 ing the goals, the review times for abbreviated new animal  
4 drug applications, and the administrative procedures  
5 adopted by the Food and Drug Administration to ensure  
6 that review times for abbreviated new animal drug applica-  
7 tions are not increased from their current level due to ac-  
8 tivities under the user fee program.

9 (c) FISCAL REPORT.—Beginning with fiscal year  
10 2004, not later than 120 days after the end of each fiscal  
11 year during which fees are collected under the part de-  
12 scribed in subsection (a), the Secretary shall prepare and  
13 submit to the Committee on Energy and Commerce of the  
14 House of Representatives and the Committee on Health,  
15 Education, Labor, and Pensions of the Senate a report  
16 on the implementation of the authority for such fees dur-  
17 ing such fiscal year and the use, by the Food and Drug  
18 Administration, of the fees collected during such fiscal  
19 year for which the report is made.

1 SEC. 5. SUNSET.

2       The amendments made by section 3 shall not be in  
3 effect after October 1, 2008, and section 4 shall not be  
4 in effect after 120 days after such date.

Passed the Senate June 3, 2003.

Attest: EMILY J. REYNOLDS,  
*Secretary.*